

NATIONAL INSTITUTES OF HEALTH
WARREN GRANT MAGNUSON CLINICAL CENTER
NURSING AND PATIENT CARE SERVICES

PROCEDURE: Controlled Substances

Approved:

_____/s/_____
Clare Hastings, RN, Ph.D.
Chief, Nursing and Patient Care Services

_____/s/_____
Charles E. Daniels, Ph.D.
Chief, Pharmacy Department

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NURSShare: Policies\Controlled Substances

Appendix (1) General Information and Procedures

I. General Information

- A. All controlled substances are stored in a secured and locked storage device or Pyxis Medstation.
- B. Controlled substances are not left at patient's bedside or otherwise unattended.
- C. Controlled substances keys are kept locked in the Pyxis Medstation or in the possession of a Registered Nurse or Licensed Practical Nurse at all times.
- D. Removal of any controlled substance from a locked storage device is documented electronically or manually at the time of removal on one of the following (see Appendix A):
 - 1. Pyxis Medstation removal pathway
 - 2. Controlled Substance Record NIH 2699-1 (10-93) (CDAR)
 - 3. Controlled Substance Infusion Record (CSIR)
- E. The inventory of controlled substances is documented electronically or manually on one of the following:
 - 1. Pyxis Medstation Inventory pathway
 - 2. Controlled Substance Inventory form NIH 2699-2 (7-91)
- F. The Pharmacy prepares all controlled substance infusions containing multiple doses or for continuous infusion, in accordance with POL: Parenteral Admixtures.

II. Ordering and Transfer of Controlled Substances

- A. Controlled substances may be ordered through
 - 1. MIS/Pharmacy Floor Stock/Controlled Substances Pathway
 - 2. MIS/Med Reorder Pathway
- B. The Pharmacy refills controlled substances into the Pyxis Medstation Monday through Friday during normal business hours. After normal business hours, controlled substances are picked up from the Pharmacy Department. The refill transaction in the Pyxis Medstation is completed by a nurse immediately upon return to the PCU.
- C. A nurse/designee with a valid Clinical Center ID may pick up and/or deliver controlled substances to the Pharmacy at any time.
- D. The persons delivering and receiving the controlled substance document the transaction by recording
 - 1. The date/time and the signatures of both parties on the CDAR or CSIR.
 - 2. The date/time as well as the signatures of both parties and their NIH ID numbers on the Pharmacy's delivery receipt.
- E. Requests for return of a controlled substance to the Pharmacy are entered into the MIS/Pharmacy Floor Stock Pathway. The Pharmacy will pick up the drug on the same day if the request is received before 10:00 a.m. Monday through Friday.
- F. A nurse manager/designee can initiate requests for permanent additions to the controlled substance inventory. A completed "Pyxis Medstation Adjustment Request" is sent to the Pharmacy Pyxis Medstation Coordinator, who then notifies the nurse manager of the decision.

III. Inventory of Controlled Substances

- A. A Pyxis Medstation Discrepancy Report is performed every 8 hours by the charge nurse. All discrepancies are investigated, resolved and documented in the Pyxis Medstation within seven (7) days. Unresolved discrepancies, and resolved discrepancies where the reason can't be entered into the Pyxis Medstation, must be recorded in the Occurrence Reporting System (ORS).
- B. An inventory of all controlled substances in the Pyxis Medstation is completed once a week by the nurse manager/designee. The electronic record of the inventory process is regularly reviewed by the Pharmacy and a nurse manager is notified of irregularities.
- C. Controlled substances not stored in a Pyxis Medstation are inventoried every 8 hours by the charge nurse/designee. In areas staffed exclusively with 12-hour shifts, the inventory may be done every 12 hours, i.e., 7 a.m. and 7 p.m. On PCUs that close at the end of a work day, controlled substances are inventoried at the end of every work day. A record of the inventory process is documented on the Controlled Substance Inventory NIH 2699-2 (7-91) and is stored on the PCU for up to 3 years.

D. Pyxis Medstation Downtime

1. In the event of a Pyxis Medstation downtime that cannot be rectified by Pyxis Medstation technical support, the Pharmacy will unlock the Pyxis Medstation to allow access to drug products and deliver the "Pyxis Downtime Dispensing Record."
2. The Pyxis Downtime Dispensing Record serves as a record of all controlled substances removed and/or wasted from a Pyxis Medstation during a downtime period. When the Pyxis Medstation has returned to normal function, this record is then used by a nurse to manually enter into the Pyxis Medstation those controlled substances removed and/or wasted.
3. When the downtime period has ended, the Pharmacy will be notified to lock the Pyxis Medstation. Until that time, nursing personnel are responsible for the security of controlled substances.
4. A full inventory of the Pyxis Medstation is completed within 8 hours of the recovered system.

IV. Documentation of Removal, Waste, and/or Return

- A. When a controlled substance is removed from the Pyxis Medstation or the locked storage device, the nurse documents (electronically or manually) the patient's name, date/time, and amount of drug removed, remaining balance, and their signature.
- B. Once a controlled substance is removed from the Pyxis Medstation or the locked storage device, any unused portion of that drug is wasted in the presence of a witness. Documentation of the waste must include date/time, name of drug, amount of drug given, amount of drug wasted, and signatures of the persons wasting the drug and witnessing the waste.
- C. If a controlled substance is removed from the locked storage device but is not needed and the package is still intact, the controlled substance is returned to the locked storage device. The return is documented and includes date, name of drug, and amount of drug returned, new balance, and signature of the person returning the drug. This transaction does not require a witness.

D. Controlled Substance Infusions

1. When a controlled substance infusion is started, the following information is recorded on the CSIR:
 - date and start time
 - rate of administration
 - signature of the nurse starting the infusion
 - signature of the nurse performing the independent double check
2. When the controlled substance infusion is completed, an entry is made on the "Completed" line of the CSIR indicating the following information:
 - date and end time
 - rate of administration at the time the infusion is completed
 - signature of nurse completing infusion
 - volume received by patient, volume wasted (if applicable), and current balance.
 - If the volume wasted is greater than "0", another individual is required to witness the waste and their signature is required.

- E. **Transdermal Controlled Substance units** (e.g. Fentanyl patch or Duragesic®) - When a transdermal controlled substance is removed from a patient, it is cut into several pieces and discarded in a sharps container for patient/visitor safety in the presence of a witness. The date/time of the action and name of the witness are recorded in the medical record.

F. Transmucosal Controlled Substance units (e.g., Fentanyl citrate or Actiq®)

1. The handle of a fully consumed transmucosal unit is discarded in a sharps container for patient/visitor safety.
2. A partially consumed transmucosal unit is dissolved in running hot water in the presence of a witness. The date/time and name of the witness are recorded in the medical record. A nurse additionally documents in the medical record that the administered drug was only partially consumed. The handle is discarded in a sharps container.
3. An opened but unused transmucosal unit is dissolved in running hot water in the presence of a witness. The date/time and name of the witness are recorded in the Pyxis Medstation as a wasted drug. The handle is discarded in a sharps container.

V. Management of a Controlled Substance Brought From Home

- A. Generally, a patient is discouraged from bringing a personal supply of a controlled substance into the Clinical Center. A nurse makes every effort to send a controlled substance home with a patient/designee.
- B. **Management of a controlled substance brought from home and not to be administered** - When a controlled substance cannot be sent home, it is inventoried by a nurse, a witness, and the patient/designee, and subsequently stored on the PCU in a locked storage device. The nurse documents (electronically or manually) in the medical record the name of the controlled substance, quantity, their name, the name of the witness, and the patient or their authorized representative.
- C. **Management of controlled substances brought from home and to be administered during hospitalization** - If a controlled substance brought from home must be used by the patient during hospitalization, i.e., the Pharmacy cannot supply the required product, the following steps are added to the above process:
 - 1. The Pharmacy identifies the drug in accordance with Medical Administrative Series Policy M94-15 Policy and Procedure for Patient Medications Brought into the Clinical Center upon Admission.
 - 2. The Pharmacy returns the identified controlled substance to the PCU with a CDAR NIH 2699-1, which remains with the controlled substance until the supply is exhausted or the patient is discharged. Both are stored in a PCU's locked storage device.
 - 3. All withdrawals and/or wastes are documented on the CDAR NIH 2699-1 as outlined above.
 - 4. The controlled substance brought from home is inventoried every 8 hours and documented on a Controlled Substance Inventory NIH 2699-2 (7-91) as described above.
- D. **Returning controlled substances to the patient at discharge**
 - 1. At the time of discharge, the controlled substance brought from home is returned to the patient.
 - 2. If a patient's controlled substance is not returned at time of discharge, for whatever reason, the controlled substance is wasted by a nurse in the presence of a witness.
 - 3. The following information is documented:
 - a. In the medical record (electronically or manually), the name of the controlled substance, number of units returned to the patient or destroyed, and disposition of the controlled substance, i.e., returned to patient or destroyed.
 - b. CDAR NIH 2699-1 (if applicable) is updated and signed by a nurse indicating the date/time and the final disposition of the controlled substance, i.e., balance returned to the patient or, balance destroyed.
 - c. Controlled Substance Inventory NIH 2699-2 (7-91) is updated to reflect the final disposition.

VI. Management of Controlled Substances when Patient Care Unit (PCU) is Closed

- A. **Closure of a PCU with a Pyxis Medstation**
 - 1. When a PCU with a Pyxis Medstation closes temporarily (weekend, holiday or period of 2 weeks or less), the Pyxis Medstation remains on that PCU in a secured area. A weekly inventory of controlled substances is still required.
 - 2. When a PCU with a Pyxis Medstation is closed for more than 2 weeks, the disposition of the Pyxis Medstation and its contents is determined jointly by the Pharmacy and nurse manager/designee.
 - 3. If at any time the Pyxis Medstation must be physically relocated in order to be in a secured area, the Pharmacy is notified and coordinates the relocation and reactivation of the Pyxis Medstation.
 - 4. When the controlled substances are transferred back to the PCU, a controlled substance inventory is performed according to this policy.
- B. **Closure of a PCU without a Pyxis Medstation**
 - 1. When a PCU without a Pyxis Medstation closes temporarily (weekend, holiday or period of 2 weeks or less), controlled substances are secured in a galvanized steel, double-locked cabinet or single locked cabinet behind a secured door. The controlled substances keys of the closed PCU are stored in a locked storage device located on a staffed PCU.
 - 2. When a PCU without a Pyxis Medstation is closed for more than 2 weeks, after conducting an inventory of the drugs, a nurse manager/designee transfers all controlled substances and associated records to the Pharmacy.

- a. The RN places the controlled substances, CDARs and the Controlled Substances Inventory form in a locked bank bag supplied by the Pharmacy. The bag is immediately locked and the bag key stored with the controlled substance keys on a staffed PCU.
 - b. The controlled substances along with the CDARs and the Controlled Substances Inventory Form are then delivered to the Pharmacy Department.
 - c. The PCU, date/time, and nurse manager/designee's signature and Clinical Center ID number are recorded in a Pharmacy Department log book for identification and record keeping purposes.
3. When the controlled substances are transferred back to the PCU, a controlled substance inventory is performed according to policy.

VII. Recordkeeping Requirements - All Controlled Substance records are completed in accordance with this policy. Follow-up on incomplete or missing records is the responsibility of the nurse manager. The following steps are taken by the Pharmacy when a record is incomplete or missing:

- A. The nurse manager is notified in writing and given seven (7) days to resolve.
- B. If the missing or incomplete records cannot be resolved, the Service Chief is notified and given seven (7) working days to resolve.
- C. If the missing or incomplete records still cannot be resolved, the Pharmacy Chief and Nursing & Patient Care Services Chief are notified in writing.

Appendix (2)

TABLE OF CONTROLLED SUBSTANCE RECORDS

CONTROLLED SUBSTANCE RECORDS (all forms are issued by Pharmacy)	PURPOSE AND FUNCTION	FILING INSTRUCTIONS
Controlled Substance Record NIH 2699-1 (10-93) (CDAR) <ul style="list-style-type: none">• aka Blue Sheet	A record of controlled substances removed and/or wasted from a patient's own supply.	Returned to the Pharmacy when the drug has been returned to the patient and/or destroyed. Place in the "completed records" section of the Controlled Substance Book. A p
Controlled Substance Record (a drug-specific form generated by Pyxis and a pharmacist)	A controlled substance record issued by the Pharmacy when a Clinical Center formulary controlled substance is dispensed to a PCU and it is not to be stored in the Pyxis Medstation. The record is then used by a nurse to document the removal and/or waste of a controlled substance.	Returned to the Pharmacy when the drug supply is exhausted or no longer needed.
Controlled Substance Infusion Record (CSIR) <ul style="list-style-type: none">• aka Pink Sheet	A record of controlled substance infusions including documentation of pick-up and delivery of the product from the Pharmacy, infusion start and end times, and waste procedures.	Returned to Pharmacy when drug infused or wasted
Controlled Substance Inventory NIH 2699-2 (7-91)	A record of controlled substance inventories conducted on those products not stored in the Pyxis Medstation.	Filed on the PCU by the nurse manager for up to 3 years.
Pyxis Downtime Dispensing Record	A record of all controlled substances removed and/or wasted from a Pyxis Medstation during a downtime period. When the Pyxis Medstation has returned to normal function, the Pyxis Downtime Dispensing Record is used by a nurse to manually enter into Pyxis those controlled substances removed and/or wasted.	Returned to Pharmacy after Pyxis Medstation has returned to normal function.